Maryland Board of Pharmacy Public Meeting Minutes November 14, 2007

Today's Attendance Year-to-Date Attendance

| | | ttenuance | T car-to-Date | e Attenuance | |
|-------------------------|---|-----------|---------------|--------------|--------|
| Name | Title | Present | Absent | Present | Absent |
| Anderson, C. | Commissioner | X | | 10 | 1 |
| Bonnett. M. | Commissioner | | X | 6 | 5 |
| Bradley-Baker, L. | Commissioner | X | | 3 | 1 |
| Chason, D. | Commissioner/Secretary | X | | 11 | 0 |
| Finke, H. | Commissioner | | X | 9 | 2 |
| Handelman, M. | Commissioner | X | | 10 | 1 |
| Israbian-Jamgochian, L. | Commissioner | X | | 4 | 0 |
| Leandre, A. | Commissioner | X | | 10 | 1 |
| Souranis, M. | Commissioner/Treasurer | X | | 9 | 2 |
| Taylor, D. | Commissioner/President | X | | 11 | 0 |
| Taylor, R. | Commissioner | X | | 10 | 1 |
| Zimmer, R. | Commissioner | Х | | 4 | 0 |
| Bethman, L. | Board Counsel | X | | 11 | 0 |
| Costley, S. | Licensing Manager | X | | 9 | 2 |
| Jeffers, A. | Legislation/Regulations Manager | X | | 10 | 1 |
| Eversley, C. | Compliance Investigator | X | | 10 | 1 |
| Naesea, L. | Executive Director | X | | 11 | 0 |
| Gaither, P. | Administration and Public Support Manager | X | | 11 | 0 |
| Goodman, S. | Public Information Officer | | X | 9 | 2 |
| Banks, T. | MIS Manager | X | | 10 | 1 |
| Taylor, A. | Compliance Officer | X | | 1 | 0 |

| Subject | Responsible Party | Discussion | Motion | Action/Results |
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| I. Introductions | Donald Taylor | Members of the Board with a conflict of interest relating to any item on the agenda were asked to notify the Board at this time. There were no recusals. | | Action Item: No action required |
| II. Approval of Minutes | Donald Taylor | Donald Taylor introduced and welcomed Dorcas Ann Taylor, the new Compliance Officer of the Board. Ms. Taylor gave a synopsis of her work experience. | | |
| | | Revisions to October 17, 2007 Minutes: -Page 3 – under action/results – change action to – "The Board voted unanimously to approve the "licensing of the Wholesaler Prescription Drug or Device" and move down next to the motion. page 4 – Change the spelling of the word "statue" to "statute" throughout the minutes" page 4 – create a separate bullet for "under the Prescription Drug Repository" page 5 – create action item – Linda Bethman to determine whether .03G was quoted from the statute. If so, then leave as is. If not, reword it so that "rejection of the application" is deleted and "Notice of Intent to Deny" is submitted. page 6 – Pharmacist On Line Renewal Database, under action item – add a "s" to the word "password" page 7 – under Internet/Website – in the next to the last sentence change MIS is "waiting" to "awaiting" page 8 – insert first sentence – "Please be advised that you must comply with the requirements of 10.34.23.08. Therefore, you must obtain the required information from the originating pharmacy". | Motion: M. Souranis moved to accept the minutes as amended. M. Handelman seconded the motion. | Board Action: The Board voted unanimously to approve the minutes as amended. |

| | | pharmaceutical" insert the word "prescription" page 8 – after last bullet – delete the word "Please" from the 1 st sentence and insert in front of 2 nd sentence. page 9 – delete The paragraph "You may access the Health Occupations Article of the Annotated Code of Maryland page 9 - under "Closed Chart" – 2 nd sentence – insert the word "for" after the word "schedule" page 10 – under "Long Term Care" – 3 rd sentence – end of sentence – delete "suitable for pharmacy." Sixth (6) sentence – after the word "that" delete the word "it." Seventh (7) sentence – after the word "recommended" delete the word "four" -The Minutes did not reflect the approval of the inspection forms that were approved at the September meeting. Completion of the forms was delegated to the Secretary. | |
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| III. Reports President/ Executive Committee Report | Donald Taylor, Board President | A. Mr. Taylor reported to the Board on the Shanghai Food and Drug Administration Delegation visit with the Board in November. The Shanghai FDA's task is to develop laws and regulations in China that will regulate the safety of Food, Drug and Devices within China and for exportation. | Action Item: No action required |
| | | B. Mr. Taylor provided an update on the DHMH Vaccine Proposed Protocol. DHMH had asked the Board to approve the agency as a Distributor. The Statue passed during the 2007 Legislation Session. The Distributor regulations due for enactment in 2008 prohibit the Board from approving this request. The local Health Departments will be ordering and receiving medications directly under a Physician's privileges. DHMH will still approve all orders. | Action Item: No Action required |
| | | C. Mr. Taylor reported that once the new inspection forms have been approved they would be utilized by the Board's Inspectors. | Action Item: No Action required |
| | | D. Dave Chason provided the end of the year report for the fiscal year 2007 budget. Mr. Chason reported that the Executive committee is awaiting the impact of the registration of Pharmacy Technicians on the budget for FY 2008. | Action Item: No Action required |
| IV. Executive Director's Report | LaVerne Naesea, Executive Director | A. Ms. Naesea announced that a Board and staff retreat is scheduled for January 16, 2008. A Public meeting beginning at 3 pm will follow the retreat. Several sites are being considered for the retreat. Public notification will be posted on the Board's website and in the Maryland Register. | Action Item: Ms. Naesea will notify Board members of the final retreat location. Public notification will be posted on the |

| | | B. Ms. Naesea reviewed items on this month's Action Item Chart. Ms. Neasea stated that she would email the chart to Board members. | | Board's website and in the Maryland Register. |
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| | | C. The Division of Drug Control Report: There were 71 pharmacy inspections including 20 opening inspections, 10 closing inspections performed during the month of October. | | Action Item: Ms. Naesea will e-mail the Action Items Chart to Board members. |
| V. PEAC | Tony Tommassello P.E.A.C. | A. Dr. Tommassello reported that PEAC's caseload consists of 14 cases, of which two (2) are pharmacy students and one (1) is a technician. PEAC received reports on 28 urine samples with all negative results. B. Dr. Tommassello reported on the October 18 th seminar in Silver Spring, Maryland at Riderwood Village. He announced that a monitor meeting will be held November 29 th to discuss the future of the Committee. The meeting will be held in Columbia at Clyde's Restaurant beginning at 6 pm. | | Action Item: No action required |
| VI. Legislation and Regulations | Anna Jeffers Legislation & Regulation Manager Report | Legislation: A. Ms. Jeffers presented the "Maryland Board of Pharmacy Prescription Drug Repository Program Annual Report to the Governor and the General Assembly" for the Board's approval. | Motion: C. Anderson moved to approve the report as presented. R. Zimmer seconded the motion. | Board Action: The Board voted unanimously to approve the motion. |

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| B. Mr. Jeffers presented the "Maryland Board of Pharmacy Wholesale Distributor Permitting and Prescription Drug Integrity Act Annual Report to the Governor and the General Assembly" for Board approval. The Board requested a revision indicating that the regulations were revised today to include language clarifying routine inspections of wholesale distributors upon initial application and renewals. | Motion: R. Zimmer moved to approve the report as amended. R. Taylor seconded the motion. | Board Action: The Board voted unanimously to approve the motion. |
| C. Status of the Physicians and Pharmacists – Therapy Management Contracts Extension of Program proposed legislation: Ms. Jeffers reported that the Department of Health and Mental Hygiene has not yet made a determination regarding whether this legislation will be sponsored by DHMH. Preliminary calls have been made to the legislative sponsors of the original legislation. Delegate Elliot will consider sponsoring the Bill if DHMH does not. | | Action Item: No Action required Action Item: A. Jeffers to follow up with DHMH and Delegate Elliott. |
| A. Status of submission for the proposed COMAR 10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors The Board approved a revision to COMAR 10.34.22 to include language clarifying routine inspections of wholesale distributors upon initial application and renewals. | Motion: L. Israbian-Jamgochian moved to approve the revisions to COMAR 10.34.22. L. Bradley-Baker seconded the motion. | Board Action: The Board voted unanimously to accept the motion. |

| | | B. Status of the Pharmacy Technician Re-proposal: Ms. Jeffers reported that two official comments have been received and they will be considered at the November Practice Committee meeting. | Action Item: Practice Committee to report their recommenda- tions at the December Board meeting. |
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| | | C. 10.06.01 Communicable Diseases and Related Conditions of Public Health Importance – Sets forth regulations for the Expedited Partner Therapy Pilot Program, SB 349 – Comments are due November 26, 2007. Ms. Jeffers asked the Board to review 10.06.01 "Communicable Diseases and Related Conditions of Public Health Importance" and provide her with any comments by Monday, November 19, 2007. | Action item: Board members to give Ms. Jeffers their comments by November 19 th . |
| | | Other News: A. RFID Conference: A. Jeffers and D. Taylor reported on the RFID Conference in Washington, DC. They attended educational sessions regarding the available technology, privacy issues and implementation issues. | Action Item: No Action required |
| | | B. MPC Legislative Conference Ms. Jeffers will present at the MPhA mid-year meeting at the Sheraton in Columbia on January 27, 2008 regarding the legislative/regulatory process and 2008 Legislation of interest to pharmacy. | Action Item: No Action required |
| VII. Administration & Public Support | Patricia Gaither, Administration and Public Support Manager | Ms. Gaither reported that applications are now being accepted for the Health Occupation Investigator I position. Interviews for the position will start after Thanksgiving. The reclassification of the Administrative Officer position will allow recruitment for a permanent receptionist/secretary. Position postings for the five (5) inspectors will be submitted November 16, 2007. Ms. Gaither is anticipating that the inspector positions will be filled by January 2008. | Action Item: Interviews scheduled to begin after Thanksgiving holiday for the Health Occupations I position. |

| VIII. Administration & Public Support | Summar Goodman, Public Information Officer | Mr. Donald Taylor provided Summar Goodman's report in her absence. Mr. Taylor reported on the Emergency Preparedness training seminar that took place October 28 th . One hundred and seventy-two (172) pharmacist participated in the seminar. Mr. Taylor stated that results from the evaluations received showed that the seminar was a success. Mr. Taylor thanked Summar Goodman, Briget Melvin, Steven Kriendler and Board Commissioners for their participation at the seminar. | Action Item: No Action required |
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| IX. Management Information Services | Tamarra Banks, MIS Manager | A. In-House Database Implementation: Ms. Banks reported that she has received the signed Towson University contract on November 13, 2007. Towson University removed the section on programming the Disciplinary and Cash/Mail modules. Ms. Banks stated that the MIS unit is willing to perform the Cash/Mail functions, using the MIS Access system. The Disciplinary committee software development must be completed by Towson. Ms. Banks plans to discuss the omission of the Disciplinary and Cash/Mail from the contract with Towson University on Wednesday, November 14, 2007. | Action Item: Ms. Banks to discuss omission of the Disciplinary software development and Cash/Mail sections from the Towson University contract. |
| | | B. HIPDB Nothing to report. | Action Item: No Action required |
| | | C. Pharmacist Online Renewal Database Ms. Banks reported that there were 30 MIS login problem calls during the month of October. | Action Item: No Action required |
| | | D. Division of Drug Control/Inspections 1) Michelle Hsu investigated the differences between the number of inspections listed by the Board each month, and the number listed by DDC. Ms. Hsu discovered part of the problem is that hospital inspections are not entered in the Board's system because the form was never entered into the software system. Ms. Banks informed the Board that there are delays in entering reports each month because they must be re-typed by the Board staff when paper inspections are received. | Action Item: Staff to work with the Division of Drug Control to coordinate entry of all forms into the software system. |
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| 2) Ms. Banks reported that some opening inspections were not |
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| entered because they were submitted directly to the Licensing Unit |
| and not with the Compliance Unit. Ms. Banks is recommending that |
| all reports go to the Compliance Unit to be entered into the Board's |
| Inspection Database. Ms. Banks stated that MIS would begin to |
| enter the new inspection forms and that hospital inspection |
| forms could have the basic information entered in the meantime. |

3) Ms. Banks reported that the synchronization with the Division of Drug Control and the Board continues. A copy of the Board's inspection database will be available to the Division of Drug Control inspectors to use to verify current pharmacist licensure status.

G. Pharmacy Technician Database

Nothing to report

H. Establishment Database

The online renewal system was turned on for the renewal season on October 16, 2007. Calls regarding login problems are reported to the Licensing Unit to verify that no outstanding taxes are owed on a prior Federal Tax ID number before any change is made by the MIS Unit. A check was made to ensure consistency with other data between the online system and the Board's mainframe system Establishment Online Renewal Login problems for October were 37.

I. Ms. Banks reported that MIS had experienced some problems relating to uploading information into the mainframe. The problem was resolved within four (4) days. The online system data is now uploaded directly from the online system into the mainframe after review by the Licensing Unit. The upload job runs daily at 1 pm and 4 pm. Web site verifications are updated at 6 pm, noon and 3 pm.

Action Item:

Staff to coordinate data entry between Compliance and Licensing units.

Action Item:

Ms. Banks will forward a copy of the Board's section of the inspection database to verify current pharmacist to the Division of Drug Control's inspectors.

Action Item:

No Action required

Action Item:

No Action required

Action Item:

No Action required

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| | | J. Personnel The Disaster Recovery/Help Desk contract ends in December 2007. MIS will submit for approval a new contract specification for additional services to be performed related to testing Disaster Recovery systems. The technician registration and pharmacy inspection data will be applied into the Disaster Recovery program this week. | | Action Item: Ms. Banks will submit for approval a new contract specification for additional services to be performed related to testing Disaster Recovery systems. |
| | | K. Internet/Web Site Ms. Banks reported on the monthly count of Board emails received. The Board's intern performed a detailed review of the Board's web pages, including a recommendation for new consumer links. After review by the unit managers, this information will be passed to MIS to incorporate on the public web site. Ms. Banks discussed the opportunity to reduce the number of Board sponsored WebSites. | | Action Item: Ms. Banks to provide the Board with a recommendation for reducing the number of WebSites. |
| | | L. Secured Web Site MIS is awaiting recommendations from the Board on information types of be placed on the secured site. | | Action Item: Board Commissioners to provide recommendations. |
| | | M. Hardware/Software Ms. Banks reported that a former Board Commissioner has not returned his loaned PC. Ms. Banks re-issued a previously used PC to LaVerne Naesea. LaVerne Nasea's PC was issued to Ann Taylor, Compliance Officer. Two Tough Book PC's are on loan from Panasonic for a 30 day Trail. Inspection forms will be loaded on to the Tough Book PC's for testing in the field. | | Action Item: Continue to contact former Board Commissioner in order to have his PC returned. |
| X. Practice Committee | Dave Chason, Chair | Constituent Questions and Responses Ms. Steward of ExcelleRx, Inc. contacted the Board concerning whether a nonresident pharmacy from Pennsylvania may provide free-standing hospice inpatient unit (IPU) patients in Maryland with medication by using an AMS Unit Based Cabinet. Some of the | Motion: D. Chason moved to refer the | Board Action: The Board voted to accept the motion. |

| 2. Recommendation that a Task Force be formed to revise COMAR 10.34.25 Delivery of Prescriptions. The Practice Committee proposed formation of the Task Force to revise COMAR 10.34.25 "Delivery of Prescriptions" Regulations to assure that drug stability and patient safety are assured. **Motion: C. Chason moved that the recommendation be referred back to the Practice Committee. C. Anderson seconded the motion.** | nonresident pharmacies continue to provide medication management services and drug therapy evaluations. The nonresident pharmacy would like to continue to provide medications to their customers through a Unit Based Cabinet. | Steward letter back to the Practice Committee. C. Anderson seconded the motion. | |
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| | 10.34.25 Delivery of Prescriptions. The Practice Committee proposed formation of the Task Force to revise COMAR 10.34.25 "Delivery of Prescriptions" Regulations to assure that drug stability | Chason moved that the recom- mendation be referred back to the Practice Committee. C. Anderson seconded the | Board voted to |

| XI. Licensing | Michael | M. Souranis provided the Li | censing Report for | the month of October. | | |
|---------------|--------------------|--|--|--|---|---|
| Committee | Souranis, Chair | Establishments: | | | | |
| | Chair | Establishments: | October 2007 | October 2006 | | |
| | | New: | 6 | 22 | | |
| | | Distributor-In State | 1 | 1 | | |
| | | Distributor- Out of State | 4 | 15 | | |
| | | Resident Pharmacy | 1 | 2 | | |
| | | Non-Resident Pharmacy | 0 | 3 | | |
| | | Pharmacy w/Waiver | 0 | 1 | | |
| | | Filalifiacy w/waivei | U | <u> </u> | | |
| | | Closed: | 2 | 3 | | |
| | | Distributor-In State | 0 | <u> </u> | | |
| | | Distributor-Out of State | 1 | 3 | | |
| | | Pharmacy | 1 | ა - | | |
| | | Non-Resident Pharmacy | 0 | <u>-</u> | | |
| | | Pharmacy w/Waiver | 0 | | | |
| | | Pharmacy w/vvalver | U | - | | |
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| | | R. Taylor provided details to Board's response to the Drusubmitted to the Board of P The Drug Therapy Manager deny all Drug Therapy Manacover mental health disease Management Committee re Protocols including Metabol Cessation. | ug Therapy Manage harmacy and the Bo ment Committee ha agement Collaborates and conditions. To commended to app | ement Protocols coard of Physicians. s recommended to ive Agreements that The Drug Therapy rove three of the | Motion: M. Handelman moved to approve the letter to be sent to the Board of Physicians. | Board Action: The Board voted unanimously to approve the letter. |
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| X. Long Term Care | Mayer Handelman, Chair | A. Mr. Handelman reported that Fox News will send him a copy of the television program regarding treatment of patients in assisted living facilities. He asked to show the program at the next Board meeting. B. Mr. Handelman is awaiting a response from Mr. Vaughn | M. Souranis seconded the motion. | Action Item: M. Handelman to report on response from OHCQ. |
| XI. Disciplinary | Mayer Handelman, | regarding Leave of Absence medications from LTC facilities. OHCQ proposed regulations that appear to be in conflict with existing pharmacy regulations. | | |
| | Chair | Cases to be discussed during the Administration Session | | Action Item: No action required |
| XII. Informational | Donald Taylor, President | A. Mr. Taylor reported on the letter from the University of Georgia informing students, alumni, faculty, staff and colleagues that their Board Regents is involved in a legal matter regarding the NAPLEX and MPJE (The National Association of Board of Pharmacy vs. The Board of Regents of the University System of Georgia and Flynn Warren, Jr., United States District Court For the Middle District of Georgia.) | | |
| | | B. Mr. Taylor described an Associated Press report that the FDA will allow the sale of Zyrtec D without a prescription. | | Action Item: No action required |
| | | C. He also reported that some physicians who are dispensing are selling prescriptions and accepting third party plans. The only requirement for physicians who dispense is to be licensed by the Board of Physicians. The Board expressed its concerns with respect to Physician dispensing since the goal is to assure protection of the public health and the integrity of the distribution system of prescription drugs. As part of the Regulatory Review and Evaluation Act, Anna Jeffers will be examining submitted public comments regarding Subtitle 13 Drugs Chapter 01 Dispensing of Prescription Drugs by a Licensee at the next Practice Committee meeting. | | Action Item: Anna Jeffers to review submitted public comments regarding Subtitle 13 Drugs Chapter 01 Dispensing of Prescription Drugs by a Licensee and present at January's Public Board Meeting. |

| XII. Adjournment | Donald Taylor, President | D. Mr. Taylor also announced Alland Leandre has been selected as the winner of one of the most prestigious and competitive honors in engineering and technology management, the 2008 Black Engineer of the Year Entrepreneur Award. The Public Meeting was adjourned at 11:57 pm. Immediately thereafter, D. Taylor convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the Exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session. M. Bonnett and A. Leandre were absent for the Public Session but attended the Administrative Session. | Motion: M. Sournais Moved to adjourn the Public Meeting. M. Handelman seconded the motion. | Board Action: The Board voted adjourn the Public Meeting. |
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